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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/888,199 | 06/23/2001 | David O'Leary | TEVNHC 3.0-031 | 8435 |
| 530 | 7590 | 02/05/2008 | EXAMINER | |
| LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | PATEL, NIHIL B | |
| | | ART UNIT | | PAPER NUMBER |
| | | 3772 | | |
| | | MAIL DATE | DELIVERY MODE | |
| | | 02/05/2008 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/888,199 | O'LEARY, DAVID | |
| | Examiner | Art Unit | |
| | Nihir Patel | 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 3.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2 and 16 is/are rejected.
- 7) Claim(s) 3-15 and 17 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on January 17th, 2008, with respect to claim 1 have been fully considered and are persuasive. The previous rejection(s) of the office action dated June 12th, 2007 has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ambrosio et al. (US 6,240,918).

4. As to claim 1, Ambrosio teaches an apparatus that comprises a sealed reservoir 22 (see figure 3; column 9 lines 50-60) including a dispensing port (see figure 5; column 10 lines 35-50); a linear channel communicating with the dispensing port and including a pressure relief port 186 (see column 19 lines 25-35; the powder retainer acts like a pressure relief port since it is made out of woven mesh); a conduit 64 providing fluid communication between an interior of the sealed reservoir and the pressure relief port 186 of the channel; a cup assembly 180 movably received in the channel and including a recess 184 adapted to receive medicament from the reservoir when aligned with the dispensing port (see column 15 lines 10-20), a first sealing

surface adapted to seal the dispensing port when the recess is not aligned with the dispensing port (**see column 26 lines 55-65**) and a second sealing surface adapted to seal the pressure relief port when the recess is aligned with the dispensing port and to unseal the pressure relief port when the recess is not aligned with the dispensing port (**see column 26 lines 63-67 and column 27 lines 1-15**).

5. **As to claim 2,** Ambrosio teaches an apparatus wherein the cup assembly includes a sealing spring 290 biasing the first sealing surface against the reservoir (**see figure 3**).
6. **As to claim 16,** Ambrosio teaches an apparatus wherein the reservoir includes a volume of dry powdered medicament (**see column 9 lines 40-50**).

Allowable Subject Matter

7. Claims **3-15 and 17** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed. The prior art also does not teach a cup assembly that includes a cup received in a cup sled movable within the channel, the cup defining the recess and the first sealing surface, and the sled defining the second sealing surface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772


Nihir Patel


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SUPERVISORY PATENT EXAMINER
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